

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	LIAMOS ET AL.	Examiner:	Unknown (K. OLSEN in parent application)
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Title:	SMALL VOLUME IN VITRO ANALYTE SENSOR AND METHODS		

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By: 

Name: Chris Stordahl

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Preliminary Amendment is being filed concurrently with a continuation application under 37 C.F.R. 1.53(b). Prior to Examination of this application, please amend the application as follows:

In the Claims

Cancel claim 1.

Add the following new claims 23-42.

1003-1004-1005-1006-1007-1008-1009-1010-1011-1012-1013-1014-1015-1016-1017-1018-1019-1020-1021-1022-1023-1024-1025-1026-1027-1028-1029-1030-1031-1032-1033-1034-1035-1036-1037-1038-1039-1040-1041-1042-1043-1044-1045-1046-1047-1048-1049-1050-1051-1052-1053-1054-1055-1056-1057-1058-1059-1060-1061-1062-1063-1064-1065-1066-1067-1068-1069-1070-1071-1072-1073-1074-1075-1076-1077-1078-1079-1080-1081-1082-1083-1084-1085-1086-1087-1088-1089-1090-1091-1092-1093-1094-1095-1096-1097-1098-1099-1100-1101-1102-1103-1104-1105-1106-1107-1108-1109-1110-1111-1112-1113-1114-1115-1116-1117-1118-1119-1120-1121-1122-1123-1124-1125-1126-1127-1128-1129-1130-1131-1132-1133-1134-1135-1136-1137-1138-1139-1140-1141-1142-1143-1144-1145-1146-1147-1148-1149-1150-1151-1152-1153-1154-1155-1156-1157-1158-1159-1160-1161-1162-1163-1164-1165-1166-1167-1168-1169-1170-1171-1172-1173-1174-1175-1176-1177-1178-1179-1180-1181-1182-1183-1184-1185-1186-1187-1188-1189-1190-1191-1192-1193-1194-1195-1196-1197-1198-1199-1200-1201-1202-1203-1204-1205-1206-1207-1208-1209-1210-1211-1212-1213-1214-1215-1216-1217-1218-1219-1220-1221-1222-1223-1224-1225-1226-1227-1228-1229-1230-1231-1232-1233-1234-1235-1236-1237-1238-1239-1240-1241-1242-1243-1244-1245-1246-1247-1248-1249-1250-1251-1252-1253-1254-1255-1256-1257-1258-1259-1260-1261-1262-1263-1264-1265-1266-1267-1268-1269-1270-1271-1272-1273-1274-1275-1276-1277-1278-1279-1280-1281-1282-1283-1284-1285-1286-1287-1288-1289-1290-1291-1292-1293-1294-1295-1296-1297-1298-1299-1300-1301-1302-1303-1304-1305-1306-1307-1308-1309-1310-1311-1312-1313-1314-1315-1316-1317-1318-1319-1320-1321-1322-1323-1324-1325-1326-1327-1328-1329-1330-1331-1332-1333-1334-1335-1336-1337-1338-1339-1340-1341-1342-1343-1344-1345-1346-1347-1348-1349-1350-1351-1352-1353-1354-1355-1356-1357-1358-1359-1360-1361-1362-1363-1364-1365-1366-1367-1368-1369-1370-1371-1372-1373-1374-1375-1376-1377-1378-1379-1380-1381-1382-1383-1384-1385-1386-1387-1388-1389-1390-1391-1392-1393-1394-1395-1396-1397-1398-1399-1400-1401-1402-1403-1404-1405-1406-1407-1408-1409-1410-1411-1412-1413-1414-1415-1416-1417-1418-1419-1420-1421-1422-1423-1424-1425-1426-1427-1428-1429-1430-1431-1432-1433-1434-1435-1436-1437-1438-1439-1440-1441-1442-1443-1444-1445-1446-1447-1448-1449-1450-1451-1452-1453-1454-1455-1456-1457-1458-1459-1460-1461-1462-1463-1464-1465-1466-1467-1468-1469-1470-1471-1472-1473-1474-1475-1476-1477-1478-1479-1480-1481-1482-1483-1484-1485-1486-1487-1488-1489-1490-1491-1492-1493-1494-1495-1496-1497-1498-1499-1500-1501-1502-1503-1504-1505-1506-1507-1508-1509-1510-1511-1512-1513-1514-1515-1516-1517-1518-1519-1520-1521-1522-1523-1524-1525-1526-1527-1528-1529-1530-1531-1532-1533-1534-1535-1536-1537-1538-1539-1540-1541-1542-1543-1544-1545-1546-1547-1548-1549-1550-1551-1552-1553-1554-1555-1556-1557-1558-1559-1560-1561-1562-1563-1564-1565-1566-1567-1568-1569-1570-1571-1572-1573-1574-1575-1576-1577-1578-1579-1580-1581-1582-1583-1584-1585-1586-1587-1588-1589-1590-1591-1592-1593-1594-1595-1596-1597-1598-1599-1600-1601-1602-1603-1604-1605-1606-1607-1608-1609-1610-1611-1612-1613-1614-1615-1616-1617-1618-1619-1620-1621-1622-1623-1624-1625-1626-1627-1628-1629-1630-1631-1632-1633-1634-1635-1636-1637-1638-1639-1640-1641-1642-1643-1644-1645-1646-1647-1648-1649-1650-1651-1652-1653-1654-1655-1656-1657-1658-1659-1660-1661-1662-1663-1664-1665-1666-1667-1668-1669-1670-1671-1672-1673-1674-1675-1676-1677-1678-1679-1680-1681-1682-1683-1684-1685-1686-1687-1688-1689-1690-1691-1692-1693-1694-1695-1696-1697-1698-1699-1700-1701-1702-1703-1704-1705-1706-1707-1708-1709-1710-1711-1712-1713-1714-1715-1716-1717-1718-1719-1720-1721-1722-1723-1724-1725-1726-1727-1728-1729-1730-1731-1732-1733-1734-1735-1736-1737-1738-1739-1740-1741-1742-1743-1744-1745-1746-1747-1748-1749-1750-1751-1752-1753-1754-1755-1756-1757-1758-1759-1760-1761-1762-1763-1764-1765-1766-1767-1768-1769-1770-1771-1772-1773-1774-1775-1776-1777-1778-1779-1780-1781-1782-1783-1784-1785-1786-1787-1788-1789-1790-1791-1792-1793-1794-1795-1796-1797-1798-1799-1800-1801-1802-1803-1804-1805-1806-1807-1808-1809-1810-1811-1812-1813-1814-1815-1816-1817-1818-1819-1820-1821-1822-1823-1824-1825-1826-1827-1828-1829-1830-1831-1832-1833-1834-1835-1836-1837-1838-1839-1840-1841-1842-1843-1844-1845-1846-1847-1848-1849-1850-1851-1852-1853-1854-1855-1856-1857-1858-1859-1860-1861-1862-1863-1864-1865-1866-1867-1868-1869-1870-1871-1872-1873-1874-1875-1876-1877-1878-1879-1880-1881-1882-1883-1884-1885-1886-1887-1888-1889-1890-1891-1892-1893-1894-1895-1896-1897-1898-1899-1900-1901-1902-1903-1904-1905-1906-1907-1908-1909-1910-1911-1912-1913-1914-1915-1916-1917-1918-1919-1920-1921-1922-1923-1924-1925-1926-1927-1928-1929-1930-1931-1932-1933-1934-1935-1936-1937-1938-1939-1940-1941-1942-1943-1944-1945-1946-1947-1948-1949-1950-1951-1952-1953-1954-1955-1956-1957-1958-1959-1960-1961-1962-1963-1964-1965-1966-1967-1968-1969-1970-1971-1972-1973-1974-1975-1976-1977-1978-1979-1980-1981-1982-1983-1984-1985-1986-1987-1988-1989-1990-1991-1992-1993-1994-1995-1996-1997-1998-1999-2000-2001-2002-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23. (New) An operative combination for use in measuring bioanalyte in a sample; the combination comprising:

- (a) a sensor strip; the sensor strip comprising:
 - (i) a substrate having a first end, a second end opposite the first end, a first side edge extending between the first end and second end, and a second side edge, opposite the first side edge and extending between the first end and second end;
 - (A) the substrate first end sized for insertion into an electrical connector;
 - (ii) a sample chamber positioned between the first and second ends;
 - (iii) at least three electrodes on the substrate and in operative contact with the sample chamber, each of the electrodes including a separate electrode trace extending from the sample chamber to the first end of the substrate; and
 - (iv) an insertion monitor stripe on the substrate;
- (b) an electrical connector in electrical communication with a meter, the electrical connector having a sensor strip receiving area sized for operative receipt of the first end of the substrate; the electrical connector further comprising:
 - (i) a first contact structure comprising at least three contact leads, one each of which is positioned to engage one each of three of the at least three electrode traces of the sensor strip when the substrate is operatively positioned with the first end positioned in the sensor strip receiving area of the electrical connector;
 - (ii) a second contact structure comprising at least a first insertion lead and a second insertion lead, each of the first and second insertion leads being positioned to operatively engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area;
 - (A) the first insertion lead being positioned with a portion thereof extending across the first side edge of the sensor strip substrate to

engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector; and,

- (B) the second insertion lead being positioned with a portion thereof extending across the second side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector;
 - (c) the sensor strip being removably mounted to the electrical connector with the substrate first end received in the sensor strip receiving area.
24. (New) An operative combination according to claim 23 wherein:
- (a) the insertion monitor stripe extends across the substrate from the first side edge to the second side edge.
25. (New) An operative combination according to claim 23 wherein:
- (a) the substrate has a first end edge adjacent the first end; and
 - (b) each one of the at least three electrode traces terminates at the first end edge of the substrate first end.
26. (New) A kit for use in measuring bioanalyte in a sample; the kit comprising:
- (a) a sensor strip; the sensor strip comprising:
 - (i) a substrate having a first end, a second end opposite the first end, a first side edge extending between the first end and second end, and a second side edge, opposite the first side edge and extending between the first end and second end;
 - (A) the substrate first end sized for insertion into an electrical connector;

- (ii) a sample chamber positioned between the first and second ends;
 - (iii) at least three electrodes on the substrate and in operative contact with the sample chamber, each of the electrodes including a separate electrode trace extending from the sample chamber to the first end of the substrate; and
 - (iv) an insertion monitor stripe on the substrate;
- (b) an electrical connector having a sensor strip receiving area sized for operative receipt therein of the first end of the sensor strip substrate; the electrical connector further comprising:
- (i) a first contact structure comprising at least three contact leads, one each of which is positioned to engage one each of three of the at least three electrode traces of the sensor strip when the substrate is operatively positioned with the first end positioned in the sensor strip receiving area of the electrical connector;
 - (ii) second contact structure comprising at least a first insertion lead and a second insertion lead, each of the first and second insertion leads being positioned to operatively engage the insertion monitor stripe when the sensor strip first end is operatively positioned in the sensor strip receiving area;
 - (A) the first insertion lead being positioned with a portion thereof extending across the first side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector; and,
 - (B) the second insertion lead being positioned with a portion thereof extending across the second side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector.

27. (New) A kit according to claim 26 wherein:
- (a) the insertion monitor stripe extends from the first side edge of the substrate to the second side edge of the substrate.
28. (New) A kit according to claim 27 wherein:
- (a) the sensor strip substrate has a first end edge adjacent the first end, the first end edge extending between the first side edge and the second side edge;
 - (b) each one of the at least three contact leads of the first contact structure is positioned to extend across the first end edge of the sensor strip substrate to engage one of the at least three electrode traces when the sensor strip substrate first end is operatively positioned in the sensor strip receiving area of the electrical connector.
29. (New) A kit according to claim 27 wherein:
- (a) the sample chamber includes a measurement zone having a volume of no more than 1 μl .
30. (New) A kit according to claim 29 wherein:
- (a) the sensor strip is a side-filling sensor strip.
31. (New) A kit according to claim 27 wherein:
- (a) the sensor strip is a tip-filling sensor strip.
32. (New) A kit according to claim 27 wherein:
- (a) at least one of the at least three electrodes of the sensor strip is a working electrode covered by a redox mediator.

33. (New) A kit according to claim 32 wherein:
 - (a) the redox mediator comprises a transition metal complex of osmium.
34. (New) A kit according to claim 33 wherein:
 - (a) a first one of the at least three electrodes of the sensor strip is positioned opposite to, and facing, a second one of the at least three electrodes of the sensor strip, with the sample chamber positioned therebetween.
35. (New) A kit according to claim 34 wherein:
 - (a) the first one of the at least three electrodes is separated from the second one of the at least three electrodes by no more than 50 μm .
36. (New) A kit according to claim 27 wherein:
 - (a) the at least three electrodes of the sensor strip are positioned coplanar with one another.
37. (New) A kit according to claim 27 wherein:
 - (a) the sensor strip comprises first and second, non-conducting, base substrates;
 - (b) the sample chamber and the at least three electrodes are positioned between the first and second base substrates;
 - (i) one of the at least three electrodes being a reference electrode positioned on one of the first and second, non-conducting, substrates;
 - (A) the reference electrode comprising a conductive carbon electrode;and
 - (ii) a second one of the at least three electrodes is a first working electrode positioned on one of the first and second non-conducting substrates;
 - (A) the first working electrode comprising a conductive carbon electrode; and

- (iii) a third one of the at least three electrodes is a second working electrode positioned on one of the first and second non-conducting substrates;
 - (A) said second working electrode comprising a conductive carbon electrode.

38. (New) A kit according to claim 37 wherein:

- (a) the electrical connector further comprises a portion of a system that includes a sensor meter having:
 - (i) a component to selectively provide at least one of potential and current to the first contact structure;
 - (ii) a processor to selectively determine analyte concentration from sensor signals received via the electrical connector; and,
 - (iii) a display to selectively show results determined from the sensor signals.

39. (New) A kit according to claim 37 wherein:

- (a) the insertion monitor stripe is positioned on an opposite side of one of the non-conducting base substrates from the sample chamber.

40. (New) A method of measuring bioanalyte in a sample; said method including a step of:

- (a) inserting a first end of a sensor strip into a sensor strip receiving area of a electrical connector; the step of inserting including:
 - (i) contacting one each of at least three contact leads in the electrical connector with separate ones of at least three electrode traces on the sensor strip; and
 - (ii) contacting first and second insertion leads of the electrical connector with an insertion monitor stripe on the sensor strip:

- (A) the step of inserting including positioning the sensor strip so that the first insertion lead extends across a first side edge of the sensor strip to engage the insertion monitor stripe; and
- (B) the step of inserting including positioning the sensor strip so that the second insertion lead extends across a second side edge of the sensor strip to engage the insertion monitor strip, the second side edge being an edge opposite the first side edge.

41. (New) A method according to claim 40 wherein:

- (a) the step of inserting includes positioning the sensor strip so that each one of three contact leads in the electrical connector extends across a first end edge of the sensor strip, to engage a respective electrode trace;
 - (i) the first end edge extending between the first and second side edges.

42. (New) A method according to claim 40 wherein:

- (a) the step of inserting includes inserting a first end of a sensor strip which includes, in a portion of the sensor strip other than the first end, a sample chamber including blood therein.

REMARKS

New claims 23-42 have been added. Claim 1 has been canceled by this amendment and claims 2-22 have been canceled in the transmittal documents of the continuation application. Claims 23-42 are pending in this application. The addition of these claims does not affect the filing fee of the application. Examination of the pending claims is requested.

New claims 23-42 are directed to a sensor strip and to an electrical connector. Independent claim 23 is to the sensor strip combined with and positioned within the electrical connector. Independent claim 26 is to a kit that comprises the sensor strip and the electrical connector, usable to form the claimed combination. Independent claim 40 is to a method of inserting the sensor strip into the electrical connector to form the claimed combination. The features of the sensor strip and the electrical connector are the same for independent claims 23, 26 and 40.

Support for these claims can be found, for example, throughout pages 35-37 of the original specification, and in the illustrations of Figures 16A and 16B, and Figures 18A and 18B.

As stated above, this application is a continuation of patent application 09/435,026 filed November 4, 1999. Also being filed on the same date herewith is a divisional application of 09/435,026, the divisional having attorney docket number 12008.42USD1. The claims of the divisional application are directed to a connector.

PATENT

The Examiner is invited to contact the undersigned if there are any questions or in order to facilitate prosecution of this application.

Respectfully submitted,

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